APR 2 8 2003

K031127
Page 1 of 2

Special 510(k) Summary
Line Extension to Orthopedic Wire

Proprietary Name:	Orthopedic Wire
Common Name:	Orthopedic Wire
Classification Name and Reference:	Bone Fixation Cerclage 21 CFR §888.3010
Proposed Regulatory Class:	Class II
Device Product Code:	87 JDQ
Predicate Proprietary Name:	Orthopedic Wire
Predicate Regulatory Class:	Class II
Predicate Product Code:	assumed to be 87 JDQ (preamendment device)
For Information contact:	Debra Bing Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 Phone: (201) 831-5413 Fax: (201) 831-6038

Description/Technological Comparison

The predicate devices are cobalt chromium alloy wires. They come either as 18" wires in an autoclavable tube, or as a 120" wire coil with an autoclavable clip. The predicate devices are 0.032" and 0.040" in diameter.

The subject devices are also cobalt chromium alloy wires. They come either as 18" wires in an autoclavable tube (6 per tube), or as a 24" length, or as a 72" (6 Foot) coil. The subject devices are 0.0126", 0.0159", 0.020", 0.040" and 0.046" in diameter.

Intended Use

The subject orthopedic wires are single-use devices. Like the predicate devices, they are intended for:

- Bone fracture fixation,
- Osteotomy,
- Arthrodesis,
- Correction of deformity,
- Revision procedures where other treatments or devices have been unsuccessful, and;
- Bone reconstruction procedures.

Testing Summary

No testing was performed to demonstrate the equivalence of the subject devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2003

Ms. Debra Bing
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K031127
Trade/Device Name: Line Extension – Orthopedic Wire
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDR
Dated: April 4, 2003
Received: April 9, 2003

Dear Ms. Bing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031027

Device Name: Line Extension – Orthopedic Wire

The subject orthopedic wires are single-use devices. They are intended for:

- Bone fracture fixation,
- Osteotomy,
- Arthrodesis,
- Correction of deformity,
- Revision procedures where other treatments or devices have been unsuccessful, and;
- Bone reconstruction procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____(Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031027 4/25/03 MNM